

(b) *Proposal Approval by the Institutional ACUC.* Before a proposal for research involving the use of animal subjects will be considered for NASA support, the NASA Headquarters Research or Flight Program Manager must receive a statement that the research has been reviewed in accordance with the PHS Policy (IV.C.) and approved by the appropriate ACUC at the participating institution.

(c) *Proposal Approval for Flight Experiments.* In addition to the institution's ACUC review, activities involving animal subjects to be flown on NASA spacecraft will be subject to review and approval by the Ames Research Center (ARC) ACUC. The ARC ACUC will submit each evaluation report to the ARC Director who will transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters. Animal activities to be flown onboard NASA manned spacecraft may also be subject to review by the Human Research Policy and Procedures Committee (HRPPC) at the Johnson Space Center (JSC). Animal activities utilizing the facilities of any NASA field installation are also subject to approval of that field installation's ACUC (§ 1232.105(d)).

(d) *Institutions with PHS Assurance on File.* The institution, by an approved or provisionally acceptable Assurance on file at the NIH Office for Protection from Research Risks (OPRR), Department of Health and Human Services (HHS), assures NASA that it will comply with the PHS Policy. The Assurance file number must be included in the research proposal submitted to NASA.

(e) *Institutions with no PHS Assurance on File.* Proposals from institutions without an approved Assurance on file with the NIH OPRR will first be peer-reviewed for scientific merit. If the proposed research is deemed worthy of support, NASA will arrange for a special Assurance to be negotiated by the Director, Life Sciences Division, NASA Headquarters. The arrangements for a special Assurance review by NIH should be undertaken in consultation with the NASA representative to the Interagency Research Animal Committee (IRAC) and will be handled on a case-by-case basis.

(f) Foreign institutions must comply with the PHS Policy (see Section II Of PHS Policy) and this rule before being supported by NASA for any activities involving animal subjects.

§ 1232.105 Implementation procedures by NASA field installations.

(a) *Proposal Information.* The information required for proposals involving the use of animal subjects is identical to that described in § 1232.104(a).

(b) *Proposal Approval by the NASA ACUC.* Before a proposal for research involving the use of animal subjects will be considered for NASA support, the NASA Headquarters Research or Flight Program Manager must receive a statement that the research has been reviewed in accordance with PHS Policy (IV.C.) and approved by the ACUC at the appropriate field installation.

(c) *Proposal Approval for Flight Experiments.* In addition to the Field Installation ACUC review, activities involving animal subjects to be flown on NASA spacecraft will be subject to review and approval by the ARC ACUC. The ARC ACUC will submit each evaluation report to the ARC Director who will transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters. Animal activities to be flown onboard NASA manned spacecraft may also be subject to review by the HRPPC at JSC.

(d) *Approval for Use of Field Installation Facilities.* The NASA Field Installation ACUC will review and approve or disapprove those parts of proposals that call for the use of their facilities to conduct any activity involving animal subjects (e.g., Kennedy Space Center or ARC Dryden facilities used to support experiments using animal subjects). The ACUC will submit each evaluation report to the Field Installation Director who will transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters.

(e) *NASA Animal Care and Use Committees.* (1) The Director of each NASA Field Installation that is involved in animal research activities will establish an ACUC to ensure compliance with the policies and provisions of this rule. The membership of the ACUC

shall be in accordance with PHS Policy.

(2) The NASA Field Installation ACUC's will review and approve or disapprove all proposals using animal subjects. In accordance with the PHS Policy (IV.C.), the ACUC will submit each report to the Field Installation Director who will, upon request, transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters.

(3) NASA ACUC's have the authority to approve, disapprove, or require changes to be made in those components of proposals involving the care and use of animal subjects that are submitted by NASA investigators. All decisions shall be based on the response of a majority of a quorum of the members. A minority opinion including abstentions should be recorded; this record should include a justification for the opinion.

(4) The ACUC shall conduct continuing review of proposals at appropriate intervals as determined by the ACUC, but not less than once every 3 years.

(5) Proposals that have been approved by the ACUC may be subject to further appropriate review by the Authorized NASA Official, NASA Headquarters. However, the official may not approve those sections of a proposal related to the care and use of animal subjects if they have not been approved by the ACUC.

(6) Once experimental procedures are approved, no substantial changes can be made unless a formal request with appropriate justification for such a request is submitted to and approved by the appropriate ACUC. If the experiment involves exposure of the flight crew to the animal subjects, the HRPPC at JSC must review and approve the proposed modifications. Copies of ACUC approval of the proposed modifications shall be submitted to the Field Installation Director who will, upon request, transmit the report to the Authorized NASA Official, NASA Headquarters.

(7) Other functions of the field installation ACUC include:

(i) Reviewing at least once every 6 months the field installation's program for humane care and use of animals,

using the Guide as a basis for evaluation;

(ii) Inspecting at least once every 6 months all of the field installation's animal facilities (including satellite facilities), using the Guide as a basis for evaluation;

(iii) Preparing reports of the ACUC evaluations conducted as required by § 1232.105 (e)(7)(i) and (ii), and submitting the reports to the Field Installation Director. (Note: the reports shall be updated at least once every 6 months upon completion of the required semiannual evaluations and shall be maintained by the field installation and made available to the Authorized NASA Official upon request. The reports must contain a description of the nature and extent of the field installation's adherence to the Guide and this rule and must identify specifically any departures from the provisions of the Guide and this rule, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with PHS Policy, and, in the judgment of the ACUC and the Field Installation Director, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency.)

(iv) Reviewing concerns involving the care and use of animals at the field installation;

(v) Making recommendations to the Field Installation Director regarding any aspect of the field installation's animal program, facilities, or personnel training.

(f) *NASA Assurances*. Each NASA field installation involved in activities using animal subjects must assure that its programs and facilities have been evaluated and accredited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC). Written assurance of compliance with the provisions of the PHS Policy and this rule is also required from NASA field installations involved in animal activities before approval of any such activity. This Assurance should follow the sample PHS Assurance format

shown on pages 19–26 of the PHS Policy and must be submitted by the Field Installation Director to the Authorized NASA Official. The Assurance is subject to renewal every 5 years.

(g) *Recordkeeping Requirements.* (1) Each NASA field installation involved in activities using animal subjects shall maintain:

(i) An Assurance of compliance with PHS Policy and this rule (§ 1232.105 (f));

(ii) Minutes of ACUC meetings, including records of attendance, activities of the committee, and committee deliberations;

(iii) Records of applications, proposals, and proposed significant changes in the care and use of animals and whether ACUC approval was given or withheld;

(iv) Records of semiannual ACUC reports and recommendations (including minority views) as forwarded to the Field Installation Director;

(v) Records of AAALAC accreditation; and

(vi) The Field Installation's Animal Users Guide and Animal Care Facility Management Manual. The Field Installation Animal Users Guide and Animal Care Facility Management Manual should be revised at appropriate intervals.

(2) All records shall be maintained for at least 3 years; records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the ACUC shall be maintained for the duration of the activity and for an additional 3 years after completion of the activity. All records shall be furnished upon request to the Authorized NASA Official.

(h) *Reporting Requirements.* For each NASA field installation involved in activities using animal subjects:

(1) Statements of ACUC approval of research proposals, ACUC evaluation reports of flight experiment proposals and of experiment proposals utilizing field installation facilities, and the field installation's Assurance of compliance shall be submitted in the manner prescribed in §§ 1232.104(c) and 1232.105 (b), (c), (d), and (f).

(2) At least once every 12 months, the ACUC, through the Field Installation

Director, shall report in writing to the Authorized NASA Official:

(i) Any change in the field installation's program or facilities that would affect the AAALAC accreditation status;

(ii) Any change in the description of the field installation's program for animal care and use;

(iii) Any changes in the ACUC membership;

(iv) Notice of the dates that the ACUC conducted its semiannual evaluations of the field installation's program and facilities and submitted the evaluations to the Field Installation Director;

(v) A statement that the field installation has no changes to report as specified in § 1232.105(h)(2) (i), (ii), or (iii) of this rule, if there are no changes.

(3) The ACUC, through the Field Installation Director, shall promptly provide the Authorized NASA Official with a full explanation of the circumstances and actions taken with respect to:

(i) Any serious or continuing non-compliance with this rule and PHS Policy;

(ii) Any serious deviation from the provisions of the Guide; or

(iii) Any suspension of an activity by the ACUC.

(4) Reports filed under § 1232.105 (h) of this rule shall include any minority views filed by members of the ACUC.

(5) A copy of the U.S. Department of Agriculture (USDA) Annual Report will be furnished to the Authorized NASA Official.

§ 1232.106 Management authority and responsibility.

(a) *Authorized NASA Official.* The Authorized NASA Official is the NASA Administrator's representative and is responsible for all NASA activities involving animal subjects. This individual is responsible for implementation of the provisions of this rule and for ensuring that agency programs involving animal subjects comply fully with all applicable laws, regulations, and guidelines.

(b) *Field Installation Director.* The Field Installation Director is responsible for and has the authority to:

(1) Sign the field installation's Assurance, making a commitment on behalf